HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2771

December 1, 2000

**CERTIFIED MAIL**
**RETURN RECEIPT REQUESTED**

WARNING LETTER
(CIN-WL-3804-00)

Byron Crampton, President
Western Medica
875 Bassett Road
Westlake, Ohio 44145-1142

Dear Mr. Crampton:

We are writing to you because during an inspection of your firm located at the above address by the Food and Drug Administration (FDA) on September 27, 2000, our Investigator collected information that revealed that your firm recently introduced an OPC-830 Oxygen Conserving Regulator onto the market.

Under the Federal Food, Drug and Cosmetic Act (the Act), Oxygen Conserving Regulators are considered to be medical devices. These devices are identified under Title 21 Code of Federal Regulations (CFR) §868.5905 as Noncontinuous ventilators (intermittent positive pressure breathing-IPPB).

Under Section 510(k) of the Act, you are required to notify the FDA at least ninety (90) days prior to introduction of a device into commercial distribution in the United States. This requirement is accomplished by the submission of a Premarket Notification requirement (510(k). The information necessary to comply with the Premarket Notification (510(k) requirement is found in 21 CFR Part 807, Subpart E - Premarket Notification Procedures.

The FDA notified you via a letter dated July 24, 2000 that your firm would need to submit a 510(k) and receive FDA clearance prior to marketing your device. Our records do not show that your firm submitted a Premarket Notification submission 510(k) before you began offering the OPC Oxygen Conserving Regulator for commercial distribution. This was confirmed during the FDA inspection when the FDA Investigator determined that your firm had made an internal determination that no such notification was needed for this device and decided to market and distribute the OPC Oxygen Conserving Regulator as a finished device.

Because your firm does not have marketing clearance from FDA, your distribution of the OPC Oxygen Conserving Regulator is in violation of the law. In legal terms, your product is adulterated under Section 501(f)(1)(B) and misbranded under Section 502(o) of the Act. Your product is misbranded

under the Act because you did not submit a 510(k) submission that shows that the device is substantially equivalent to other devices that are legally marketed. Until your firm submits a 510(k) and receives notice from the FDA, Center for Devices and Radiological Health clearing the device for commercial distribution, the OPC Oxygen Conserving Regulator is adulterated under the Act because you did not obtain premarket approval based on information developed by you that shows that the device is safe and effective.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence to each requirement of the Act and regulations. Some regulations that are applicable to your devices include the Quality System/Good Manufacturing Practices (QS/GMP) regulation (21 CFR Part 820), the Medical Device Reporting (MDR) regulation (21 CFR Part 803), and the Corrections and Removals regulation (21 CFR Part 806).

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. Possible actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violation, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response to this Warning Letter should be sent to Evelyn D. Forney, Compliance Officer, Food and Drug Administration, 6751 Steger Road, Cincinnati, Ohio 45237.

Sincerely,

Henry L. Fielden
District Director
Cincinnati District